UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,687	02/26/2002	Ravinder C. Mehra	517427-2000.1	1509

20999 7590 01/20/2004

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
GARBER, CHARLES D	

ART UNIT	PAPER NUMBER
2856	

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,687	MEHRA ET AL.	
	Examiner	Art Unit	
	Charles Garber	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *20-34,41-49,52 and 54* is/are withdrawn from consideration.

5)☒ Claim(s) *35-40 and 53* is/are allowed.

6)☒ Claim(s) *1-19,50,55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner should note that prior to the amendment being filed claims 50 and 55 were identical to claims 1 and 10 respectively and should have been objected to for failing to further limit in the Examiner's Office Action of 06/06/2003. This objection is obviated by the Applicant's current amendment to claims 1 and 10.

Election/Restrictions

This application contains claim 20-34, 41-49, 51, 52, 54 drawn to an invention nonelected with traverse in Applicant's response filed 04/29/2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments

Applicant's arguments filed 11/07/2003 have been fully considered but they are not persuasive.

Applicant argues there is no motivation within the references themselves for a retractable needle. Preston et al. In US Patent 6,274,087 explain "Blood sample analysis systems are known in which the operator must position and hold in place tubes or vials of the samples to be analyzed. The systems include needles [that] expose operators to the risk of contamination and infection from blood samples... It is desired to have a safer, more flexible means for positioning and holding blood sample tubes and vials during the cap piercing operation. Specifically, it is desired to have a holding and piercing apparatus which is "hands off" during the piercing operation, so as to prevent exposure of the operator to contamination from the blood in the vial being penetrated. It

is also desired to improve the safety of such an apparatus by incorporating a safety interlock system" that prevents the needle from extending when there is no vial present. Examiner therefore provided that --It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for a retractable and extensible needle in a sampling device so that an operator may not be inadvertently pricked-- and thereby potentially infected by the sample or in some way contaminate the sample under study. Both the Preston reference as well as the Smith reference deal with sampling including blood and blood products (Smith discusses "blood borne contaminates" as well as offering that an "example of its use would be where the filter media would allow plasma to flow through while preventing red blood cells to pass when working with blood samples") so the teaching provided by Preston is quite relevant and applicable to Smith.

Applicant also argues the device of Preston is complex whereas the device in Smith is simple and that there is no embodiment in the Smith patent that could accommodate the mechanisms recited in the Preston patent. Examiner does not agree and Applicant has provided no evidence supporting the conclusion that the teaching of Preston would somehow destroy the functionality of Smith.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (US Patent 6,117,394).

Regarding claim 50, Smith discloses a membrane filtered pipette tip used in nucleotide sequence analysis (title and background), which is equivalent to a device for removing an aliquot or portion of biological sample. Figures 2, 3D, 4, 10C and 11C show sample being taken or aspirated from receptacle. In addition, needle 30 is provided for cases when a surface must be pierced in order to take a sample which is equivalent to removing samples from a sealed receptacle as in the instant invention.

Figures 10C, 11C and 12 illustrate a multiple pipette tip with attached well for precision volume multiple pipetting and are shown having inner and outer walls and top and bottom ends forming a hollow chamber. "These tips are designed to hold a particular pre-calculated volume" thus defining a predefined volume as in the instant invention.

Needle 30 shown in an optional embodiment is shown in figure 4B with a hollow piercing tip and blunt end wherein the blunt end is engaged to the bottom end of the hollow chamber. The piercing end may be sharp. (column 7 line 61 to column 8 line 2)

Smith also includes a membrane filter M shown in figure 2 contacting the inside wall of the hollow pipette. (column 4 lines 65+)

Claim 55 is substantively equivalent to claim 50 as discussed above except for the express intended use of the filter barrier for preventing cross-contamination of fluids, aerosols, or samples beyond said hollow chamber. However, the reference recites "tips having a first filter for filtering material drawn into the pipette tip and second filters from

preventing contamination of the pipette." (abstract) The specific placement of the filter (similar to that of the instant invention as illustrated in the specification figures) will inherently prevent contamination beyond the hollow chamber as in the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-10, 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US Patent 6,117,394) in view of Preston et al. (US Patent 6,274,087).

Regarding claim 1, Smith discloses a membrane filtered pipette tip used in nucleotide sequence analysis (title and background), which is equivalent to a device for removing an aliquot or portion of biological sample. Figures 2, 3D, 4, 10C and 11C show sample being taken or aspirated from receptacle. In addition, needle 30 is provided for cases when a surface must be pierced in order to take a sample which is equivalent to removing samples from a sealed receptacle as in the instant invention.

Figures 10C, 11C and 12 illustrate a multiple pipette tip with attached well for precision volume multiple pipetting and are shown having inner and outer walls and top and bottom ends forming a hollow chamber. "These tips are designed to hold a particular pre-calculated volume" thus defining a predefined volume as in the instant invention.

Needle 30 shown in an optional embodiment is shown in figure 4B with a hollow piercing tip and blunt end wherein the blunt end is engaged to the bottom end of the hollow chamber. The piercing end may be sharp. (column 7 line 61 to column 8 line 2)

Smith also includes a membrane filter M shown in figure 2 contacting the inside wall of the hollow pipette. (column 4 lines 65+)

Smith however lacks the piercing tip retractable within the hollow chamber.

Preston teaches needle 20 retractable within a hollow chamber as shown in figures 8A and 9A. The needle only extends when a sample vial is within a holder. (column 2 lines 1-9)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for a retractable and extensible needle in a sampling device so that an operator may not be inadvertently pricked.

Claim 10 is substantively equivalent to claim 1 as discussed above except for the express intended use of the filter barrier for preventing cross-contamination of fluids, aerosols, or samples beyond said hollow chamber. However, the reference recites "tips having a first filter for filtering material drawn into the pipette tip and second filters from preventing contamination of the pipette." (abstract) The specific placement of the filter

(similar to that of the instant invention as illustrated in the specification figures) will inherently prevent contamination beyond the hollow chamber as in the instant invention.

As for claims 4 and 13, figures 2, 3D, 4, 10C and 11C show sample being taken from a tube like receptacle.

As for claim 14, Smith further discloses that the "concept can be incorporated into any of the proposed tip configurations and would be especially beneficial in the multichannel pipetters and useful in automated pipetting machinery...."

As for claims 5 and 15, the pipette tips T and/or the piercing tip 30 is inherently disposable.

As for claims 6 and 16, Smith further discloses the filter may be hydrophobic allowing only sterile gases to pass (column 5 lines 35-40) and the filters may be made from Nitrocellulose, Cellulose Acetate, Nylon, PTFE, etc.) and are autoclavable, hydrophobic, gamma irradiation sterilable. (column 4 lines 40-60)

Regarding claims 3 and 12, Smith as discussed above does not expressly recite what types of intended biological samples may be used with the device and therefore may be used with any type of biological sample. However Examiner considers that it is widely known that any type of biological sample may include blood, plasma, spinal fluid, serum, saliva, sputum, urine, feces, Buccal cells, spermatozoa, solid tissue, bacteria, yeast, viral samples, semen, cultured cells lines, plants, and combinations thereof as in the instant invention.

One having ordinary skill in the art would have known of the advantage of sampling for purposes of analysis any material obtained from a living source (e.g.

human, animal, plant, bacteria, fungi, protist, virus). One of ordinary skill would also have known the biological sample can be in any form, including solid materials (e.g. tissue, cell pellets and biopsies) and biological fluids (e.g. urine, blood, saliva, amniotic fluid, seminal fluid and mouth wash (containing buccal cells)). Medical and pharmacological analysis and experimentation involves examination of all types of living material.

As for claim 7 and 17, Smith discloses drawing samples sized from 0.5 to 50 microliter and lacks drawing larger samples in the additional range from 51 microliter to 50,000 microliters as in the instant invention. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to samples from 51 microliter to 50,000 microliters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, the general conditions defining a pipette tip with a filter are satisfied by Smith. The instant invention does not provide any novel or non-obvious structure related to achieving a specific volume range in sampling. In fact, the difficulty in the state of the art appears to be related to achieving the very smallest of sample sizes and not the larger.

As for claims 8 and 18, Smith discloses drawing samples sized from 0.5 to 50 microliter and lacks drawing larger samples in the additional range from 51 microliter to 1,000 microliters as in the instant invention. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to samples from 51 microliter to 1,000 microliters, since it has been held that where the general

conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, the general conditions defining a pipette tip with a filter are satisfied by Smith. The instant invention does not provide any novel or non-obvious structure related to achieving a specific volume range in sampling. In fact, the difficulty in the state of the art appears to be related to achieving the very smallest of sample sizes and not the larger.

As for claims 9 and 19, Smith discloses drawing samples sized from 0.5 to 50 microliter and lacks drawing larger samples in the additional range from 51 microliter to 100 microliters as in the instant invention. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to samples from 51 microliter to 100 microliters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, the general conditions defining a pipette tip with a filter are satisfied by Smith. The instant invention does not provide any novel or non-obvious structure related to achieving a specific volume range in sampling. In fact, the difficulty in the state of the art appears to be related to achieving the very smallest of sample sizes and not the larger.

Allowable Subject Matter

Claims 35-40 and 53 are allowed.

Please see earlier Office Action for reasons for allowance.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles Garber whose telephone number is (703) 308-6062. The examiner can normally be reached on 6:30 a.m. to 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (703) 305-4705. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4900.

cdg

HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800